

## REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed January 1, 2006 ("Office Action"). Claims 72, 74-110, 112, and 114-119 are pending in the application. No claims are amended. Applicant notes with appreciation the allowance of claims 77-79, 89, 93, and 100 as well as the indication of allowability of the subject matter of claim 102. Applicant respectfully requests reconsideration as to the rejection of claims 72, 74-76, 80-88, 90-92, 94-99, 101, 103-110, 112 and 114-119 for the following reasons.

### **Anticipation -- 35 U.S.C. § 102**

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Manual of Patent Examining Procedure § 2131 (8th ed., rev. 2, May 2004) (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

At the outset, applicant agrees that claims are to be given their broadest reasonable interpretation in the Patent Office. Indeed, "[d]uring patent examination the pending claims must be interpreted as broadly as their terms reasonably allow." *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). However, as stated succinctly by the Federal Circuit, "the operative term is *reasonable*." *Genentech Inc. v. The Wellcome Foundation Ltd.*, 31 USPQ2d 1161, n. 22 (Fed. Cir. 1994)(emphasis in original). The broadest reasonable interpretation of continuously determining simply does not include taking a single, discrete measurement as shown by the cited references. The reasoning that any discrete measurement requires some time period to take and is thus continuous makes the word continuous apply to everything in the universe--even non-continuous or single, discrete measurements. Even the dictionary definition cited in the Office Action requires the word "uninterrupted," which is antithetical to a single, discrete measurement. Accordingly, when the claims are given their broadest reasonable interpretation, the cited art fails to teach every element of the claim.

The Office Action rejects claims 72, 74-76, 82, 83, 90, 97, 101, 107, 112, and 114 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,009,343 ("Shain").

Shain discloses the use of vacuum to enhance the transdermal transport of fluids in sampling methods for the detection of analytes in a patient's blood. See Abstract. According to Shain, "ultrasound is applied to a region of the skin, reduced pressure is applied to the same vicinity of the skin and any fluid which exudes the skin is collected." Shain, col. 2, ll. 20-24. Independent claim 72 includes, among other limitations, the requirement of "continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone." Shain teaches taking a single, discrete measurement. The Office Action interprets continuously to include all single, discrete measurements, since "the measurement is continuous over the time period taken to perform the measurement." Office Action, page 8. Applicant respectfully submits that this is an unreasonably broad interpretation of continuous. In order for a determination to be carried out continuously it must at the very least continue. A person of ordinary skill would know that there is a difference between a discrete or noncontinuous determination and a continuous determination. Thus, Shain fails to teach or suggest continuously determining the quantity of at least one analyte in the body fluid in the sensing zone.

Shain fails to teach each and every element of claim 72 and thus does not anticipate claim 72. Claims 74-76, 82, 83, 90, 97, and 101 are not anticipated as they depend from and incorporate the limitations of claim 72. Accordingly, the rejection of claims 72, 74-76, 82, 83, 90, 97, and 101 under 35 U.S.C. § 102(e) as being anticipated by Shain must be withdrawn.

Independent claim 107 includes, among other limitations, the requirement of "a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid." The Office Action again relies on col. 3, ll. 14-24 for a teaching of "a sensing device . . . for continuously measuring." As discussed above, nothing in Shain teaches or suggests "a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid." Shain fails to teach each and every element of claim 107 and thus does not anticipate claim 107. Claims 112 and 114 are not anticipated as they depend from and incorporate the limitations of claim 107. Accordingly, the rejection of claims 107, 112, and 114 under 35 U.S.C. § 102(e) as being anticipated by Shain must be withdrawn.

The Office Action rejects claims 72, 74-76, 80-86, 88, 90-92, 97, 98, 101, 107, 108, 112, 114, 117-119 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application No. 2002/0045850 ("Rowe").

Rowe teaches "ultrasound enhancement of transdermal transport" and a "two step noninvasive method involv[ing] application of ultrasound to increase skin permeability and removal of ultrasound followed by transdermal transport that can be further enhanced using a physical enhancer." See Abstract. Rowe teaches that "channeling of ultrasound geometrically," paragraph 14, as one way of enhancing ultrasound. Independent claim 72 includes, among other limitations, the requirement of "continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone." Rowe fails to teach *continuously* determining as it is directed simply to a single, discrete measurement of concentration. The Office Action interprets continuously to include all single, discrete measurements, since "the measurement is continuous over the time period taken to perform the measurement." Office Action, page 8. Applicant respectfully submit that this is an unreasonably broad interpretation of continuous. In order for a determination to be carried out continuously it must at the very least continue. A person of ordinary skill would know that there is a difference between a discrete or noncontinuous determination and a continuous determination. Accordingly, Rowe fails to teach or suggest continuously determining the quantity of at least one analyte in the body fluid in the sensing zone and fails to teach each and every element of claim 72. Claims 74-76, 80-86, 88, 90-92, 97-98, and 101 are not anticipated as they depend from and incorporate the limitations of claim 72. Accordingly, the rejection of claims 72, 74-76, 80-86, 88, 90-92, 97-98, and 101 under 35 U.S.C. § 102(e) as being anticipated by Rowe must be withdrawn.

Independent claim 107 includes, among other limitations, the requirement of "a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid." The Office Action points to paragraph 93 to support its contention that Rowe teaches a step of "continuously measuring." However, as discussed above with respect to a step of "continuously determining," Rowe does not include a step of continuously measuring. Instead, Rowe merely teaches measuring the concentration of glucose in an analyte solution. This can be accomplished without continuously determining the quantity of at least one analyte in the body fluid in the sensing zone. Thus, Rowe fails to teach each and every element of claim

107 and thus does not anticipate claim 107. Claims 108, 112, and 114 are not anticipated as they depend from and incorporate the limitations of claim 107. Accordingly, the rejection of claims 107-108, 112, and 114 under 35 U.S.C. § 102(e) as being anticipated by Rowe must be withdrawn.

Independent claims 117 and 118 include, among other limitations, the requirement of "continuously monitoring a change in said at least one characteristic of said gel" and "a monitoring device for continuously monitoring a change in said at least one characteristic of said gel," respectively. The Office Action points to paragraph 93 to support its contention that Rowe teaches a step of "continuously monitoring." However, as discussed above with respect to a step of "continuously determining," Rowe does not include a step of continuously monitoring. Instead, Rowe merely teaches measuring the concentration of glucose in an analyte solution. This can be accomplished without continuously determining the quantity of at least one analyte in the body fluid in the sensing zone. Thus, Rowe fails to teach each and every element of either claim 117 or claim 118 and thus does not anticipate these claims. Claim 119 is not anticipated as it depends from and incorporates the limitations of claim 118. Accordingly, the rejection of claims 117-119 under 35 U.S.C. § 102(e) as being anticipated by Rowe must be withdrawn.

### **Obviousness -- 35 U.S.C. § 103**

The Office Action rejects claims 86 and 87 under 35 U.S.C. § 103(a) as unpatentable over Shain as applied to claim 74 above, further in view of U.S. Patent No. 6,468,229 ("Grace"). Shain is discussed above with respect to the anticipation rejections. Grace is cited to teach the use of "a tensioner having a cavity to collect the fluid therein." Office Action, page 5. Since Grace is not cited to provide a teaching for continuous measurement or continuously measuring, it fails to cure the deficiencies of Shain. Accordingly, the rejection of claims 86 and 87 under 35 U.S.C. § 103(a) as unpatentable over Shain in view of Grace must be withdrawn.

The Office Action rejects claims 95 and 96 under 35 U.S.C. § 103(a) as unpatentable over Shain as applied to claim 90 above, further in view of U.S. Patent No. 6,503,198 ("Aronowitz"). Shain is discussed above with respect to the anticipation rejections. Aronowitz is cited to teach "applying a hydrophobic coating to the skin prior to fluid extraction from the skin." Office Action, page 6. Since Aronowitz is not cited to provide a teaching for continuous

measurement or continuously measuring, it fails to cure the deficiencies of Shain. Accordingly, the rejection of claim 95 and 96 under 35 U.S.C. § 103(a) as unpatentable over Shain in view of Aronowitz must be withdrawn.

The Office Action rejects claim 99 under 35 U.S.C. § 103(a) as unpatentable over Shain as applied to claim 86 above, further in view of WO 97/30749 ("Abbott").

Shain is discussed above with respect to the anticipation rejections. Abbott is cited to teach "a chemical method comprising applying a hydrophilic gel to receive the at least one analyte." Office Action, page 6. Since Abbott is not cited to provide a teaching for continuous measurement or continuously measuring, it fails to cure the deficiencies of Shain. Accordingly, the rejection of claim 99 under 35 U.S.C. § 103(a) as unpatentable over Shain in view of Abbott must be withdrawn.

The Office Action rejects claims 103-106, 109, 110, 115, and 116 under 35 U.S.C. § 103(a) as unpatentable over Shain as applied to claims 72 and 107 above, further in view of U.S. Patent No. 5,722,397 ("Eppstein"). Shain is discussed above with respect to the anticipation rejections. Eppstein is cited to teach "a method for analysis of at least one analyte in body fluid including providing an output for a user interface having an alarm that indicates an abnormal analyte concentration." Office Action, page 7. Since Eppstein is not cited to provide a teaching for continuous measurement or continuously measuring, it fails to cure the deficiencies of Shain. Accordingly, the rejection of claim 103-106, 109, 110, 115, and 116 under 35 U.S.C. § 103(a) as unpatentable over Shain in view of Eppstein must be withdrawn.

Applicant submits that this response addresses all of the issues raised in the Office Action. Applicant submits that claims 72, 74-110, 112, and 114-119 are in condition for allowance and notice to that effect is hereby solicited. Should any issues remain to be discussed in this application, the Examiner is invited to contact the undersigned by telephone.

In the event any variance exists between the amount authorized to be charge to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
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